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UNITED STATES DISTRICT COURT

DISTRICT OF UTAH

MARC RICHFIELD, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. POLARITYTE, INC., DENVER LOUGH, DAVID SEABURG, JACOB PATTERSON, PAUL MANN, and RICHARD HAGUE, Defendants.	**[~~PROPOSED~~] MEMORANDUM DECISION AND ORDER GRANTING DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED COMPLAINT** Case No. Case No. 2:21-cv-00561-BSJ Hon. Bruce S. Jenkins

Plaintiffs sued Defendants PolarityTE, Inc. ("PolarityTE"), Denver Lough, David Seaburg, Jacob Patterson, Paul Mann, and Richard Hague under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The Court granted Defendants' motion to dismiss the First Amended Complaint filed in this action and granted Plaintiffs leave to file a Second Amended Complaint to "set forth with specificity and simplicity which statements by Defendants are allegedly false, why the statements were false when made, who made the statements, and to whom the statements were made." Dkt. 74 at 1. The amended complaint fails to allege with the particularity required by the Private Securities Litigation Reform Act ("PSLRA") that Defendants made materially false or misleading statements to investors. The Court therefore grants Defendants' motion to dismiss with prejudice.

BACKGROUND

PolarityTE is a biotechnology company headquartered in Salt Lake City, Utah that develops regenerative tissue products, including a product called SkinTE™. Dkt. 54-1 at 1. The Plaintiffs' securities fraud claims are based on SkinTE's registration with the FDA, PolarityTE's biologics license application ("BLA") and investigational new drug ("IND") for SkinTE, and PolarityTE's sale of SkinTE pursuant to an enforcement discretion policy implemented by FDA from 2017 to 2021. Essentially, Plaintiffs claim that Defendants made false or misleading statements regarding (1) whether PolarityTE registered SkinTE using the correct regulatory pathway, (2) the components of PolarityTE's IND application, and (3) PolarityTE's ability to sell SkinTE based on FDA enforcement discretion.

SkinTE, FDA Regulations, and Enforcement Discretion

PolarityTE's first regenerative tissue product is SkinTE, which is designed to repair and reconstruct skin in patients with chronic wounds, burns, surgical reconstruction events, scars, or who have had dysfunctional skin grafts removed. Dkt. 54-1 at 1. PolarityTE was founded by Defendant

Dr. Denver Lough, who invented the technology underlying SkinTE as an alternative to the dominant approach to wound care. Dkt. 54-2 at 3; Dkt. 54-5 at 3–4. SkinTE is designed to address the limitations of split-thickness skin grafts—the prevailing method of wound care—by using a sample of the patient's skin tissue to develop a custom product that promotes healing and regeneration of full-thickness skin. Dkt. 54-5 at 3–4, 7–8. PolarityTE claims that it has been able to collect a sample of skin from a patient that is 5 cm^2 or less and "produce enough SkinTE to treat a wound 30x greater in size than the skin collected." Dkt. 77 ¶ 131. The company cautioned investors, however, that additional work was needed to validate that real-world experience and understand the relationship between the size of a harvested skin sample and the ultimate dosage of SkinTE. Dkt. 77 ¶ 142.

SkinTE is subject to federal regulation as a human cell and tissue product ("HCT/P"). Dkt. 54-7 at 1. An HCT/P is an article that contains or consists of human cells or tissues and is intended for use by a human recipient. *Id.*; *see also* 21 C.F.R. § 1271.3(d). The Public Health Service Act ("PHSA") creates two pathways for registration of an HCT/P with the FDA. A company can self-register an HCT/P under Section 361 of the PHSA if the product meets the criteria set forth in 21 C.F.R. § 1271.10(a). Section 361 registration is appropriate where, in addition to other requirements, an HCT/P is "minimally manipulated," meaning that processing of tissue used in the HCT/P does not "alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement." 21 C.F.R. § 1271.3(f).

Significantly, the regulations allow companies, in the first instance, to determine whether a product meets the Section 361 registration requirements (including, for example, whether the HCT/P is minimally manipulated). Dkt. 54-8 at PDF p. 18. There is no provision in the PHSA or the implementing regulations that requires consultation with or approval by the FDA prior to Section 361 registration of a product. *Id.*

If a product does not meet the requirements for Section 361 registration, then it is subject to regulation as a biological product under Section 351, which requires premarket review and approval by the FDA. Dkt. 54-7 at 3, 22. Under Section 351, manufacturers must conduct clinical trials pursuant to an effective IND application or new drug application ("NDA"). Dkt. 54-8 at PDF p.18. Marketing of a biological product under Section 351 is not allowed without a biologics license issued by the FDA. *Id.*

PolarityTE registered SkinTE under Section 361 on August 14, 2017. Dkt. 77 ¶ 68. After registering SkinTE under Section 361, PolarityTE explained to investors that while it "believe[d]" that SkinTE was "appropriately regulated by the FDA" as a "Section 361" HCT/P, Dkt. 77 ¶ 111, FDA's regulation of HCT/Ps would likely evolve in the future and regulators could disagree with the company's assessment that SkinTE qualified for Section 361 registration. *See* Dkt. 80-2 at 12–13.

The FDA published final guidance regarding HCT/P regulations in late 2017. Dkt. 54-7. FDA announced at that time that it would exercise enforcement discretion for a limited period and allow manufacturers to market an HCT/P under Section 361 even if the HCT/P did not meet all the requirements under 21 C.F.R. § 1271.10(a), as long as the use of the HCT/P did not raise safety issues. Dkt. 54-7 at 3, 21. The stated purpose of the enforcement discretion policy was to "give manufacturers time to determine if they need to submit an IND or marketing application." *Id.* at 21.

The FDA initially announced that it would exercise enforcement discretion until November 2020. Dkt. 54-9 at 22. But the Agency announced in July 2020 that it would extend the period of enforcement discretion through May 31, 2021 because of challenges caused by the COVID-19 pandemic. Dkt. 54-10 at 23. On April 21, 2021, FDA announced that it would not further extend the end of the enforcement discretion period past May 31, 2021. Dkt. 54-11.

FDA Inspection of PolarityTE's Manufacturing Facility

The FDA inspected PolarityTE's manufacturing facility in Salt Lake City from July 9, 2018 to July 13, 2018. Dkt. 54-15 at 1. The inspector identified potential violations of FDA manufacturing protocols, which were documented as "observations" in a Form 483 report. Dkt. 54-15. The Form 483 stated that observations did not "represent a final Agency determination regarding [PolarityTE's] compliance." *Id.* at 1. The matter ultimately closed with a Voluntary Action Indicated ("VAI")[1] classification and regulators did not take any compliance actions against PolarityTE. Dkt. 54-16 at PDF pp. 3, 6 . Nevertheless, PolarityTE disclosed receipt of the Form 483 and its response to the FDA's observations. Dkt. 54-5 at 16.

PolarityTE's IND Application and Marketing of SkinTE

On April 30, 2020, PolarityTE announced that it would seek registration of SkinTE under a different regulatory pathway, Section 351. Dkt. 54-18 at 1. The company explained to investors that this decision would require submission of an IND application for SkinTE and clinical trials for the product. Dkt. 54-18 at 1. The company disclosed that the decision followed informal and voluntary discussions with regulators regarding SkinTE's registration status. *Id.* FDA did not ask PolarityTE to stop marketing SkinTE under Section 361 or take any enforcement action. Dkt. 54-9 at 22.

PolarityTE provided more detail on its decision to seek Section 351 registration in its May 11, 2020 10-Q filing. *See* Dkt. 54-9 at 22, 33–36. The company explained that it planned to discuss with the FDA the possibility of marketing SkinTE as a Section 361 HCT/P on a limited basis after the end of the enforcement discretion period, but cautioned that "it is not customary for the FDA to allow wide-spread commercial sales of a product subject to a pending BLA." *Id.* at 22. The Company

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[1] A VAI classification means "objectionable conditions were found and documented but the agency is not prepared to take or recommend regulatory action." Dkt. 54-17 at 1.

ultimately stopped marketing SkinTE in May 2021, the end of the enforcement discretion period.

PolarityTE submitted its IND application for SkinTE on July 23, 2021 for Section 351 registration. Dkt. 54-20 at 1. The company warned investors in a July 26, 2021 press release that the FDA could raise questions regarding the IND application, and "potentially [issue] a clinical hold if information requests or other issues are unresolved," at which point PolarityTE "would work with FDA in an effort to resolve any outstanding issues." *Id.*

PolarityTE announced on August 24, 2021 that the FDA placed a clinical hold on the IND application pending resolution of certain chemistry, manufacturing, and control ("CMC") items. Dkt. 54-21 at 1. PolarityTE submitted a response on December 17, 2021 and the FDA lifted the clinical hold in January 2022. Dkt. 54-22 at 1; Dkt. 54-23 at 1; Dkt. 54-24.

LEGAL STANDARD

The pleading standard for Plaintiffs' complaint is two-fold. First, Plaintiffs must satisfy the typical plausibility standard, which requires a complaint to allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible when the plaintiff pleads enough "factual content" to allow the Court to "draw the reasonable inference that the defendant is liable for the misconduct alleged" in the pleading. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Court is required to accept all the "well-pleaded factual allegations" as true and "construe them in the light most favorable to the plaintiff." *Id.* at 678–79. Allegations are well-pleaded where they are "supported by factual allegations" rather than "mere conclusory statements." *Id.*

In a securities fraud case, the allegations of the complaint must also satisfy the heightened pleading standard imposed by the Private Securities Litigation Reform Act ("PSLRA") and Federal Rule of Civil Procedure 9(b). The PSLRA requires plaintiffs to specify every statement alleged to be misleading with particularity and the reasons why each statement is misleading. 15 U.S.C. § 78u–

4(b)(1)(B). The statute further requires plaintiffs to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" with respect each statement or omission. *Id.* § 78u–4(b)(2)(A). And because the claims sound in fraud, the complaint must also satisfy Rule 9(b)'s requirement to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

ANALYSIS

Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder make it unlawful for any person to make a false or misleading statement of material fact in connection with the purchase or sale of any security. 15 U.S.C. § 78j(b); 17 C.F.R. § 240.10b-5. These provisions create an implied private cause of action for fraud in the purchase or sale of securities. *Hampton v. root9B Techs., Inc.*, 897 F.3d 1291, 1298 (10th Cir. 2018).

To state a claim for securities fraud, a private plaintiff "must prove that the defendants (1) made a material misrepresentation or omission; (2) with scienter; (3) in connection with the purchase or sale of a security; (4) upon which the plaintiff relied; (5) that the plaintiff suffered an economic loss; and (6) that the material misrepresentation was the cause of that loss." *In re Williams Sec. Litig.*, 558 F.3d 1130, 1136 (10th Cir. 2009).

For the reasons explained below, the Court concludes that Plaintiffs have not stated a claim under the federal securities laws because Plaintiffs have not pleaded with sufficient particularity and specificity that Defendants made material misrepresentations or omissions.

I. Falsity

The first element of a securities fraud claim is falsity—a material misstatement or omission. The PSLRA imposes a heightened pleading standard on plaintiffs with respect to the falsity element. To survive a motion to dismiss, a complaint must "specify each statement alleged to have been misleading" and "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u–4(b)(1)(B).

The statements challenged by Plaintiffs as false or misleading fall into three categories: (A) statements concerning SkinTE's registration under Section 361; (B) statements relating to PolarityTE's manufacturing processes and the dosing for SkinTE; and (C) a statement regarding FDA enforcement discretion and marketing of SkinTE. As set forth herein, the Court concludes that Plaintiffs have not satisfied the PSLRA's requirement to specifically plead the reasons why these statements were materially false or misleading.

A. Section 361 Registration Statements

The first category of statements challenged by Plaintiffs relate to PolarityTE's registration of SkinTE under Section 361. *See* Dkt. 77 ¶¶ 111, 114, 121, 128, 140, 145. Plaintiffs contend that these statements were false and misleading because they did not disclose that SkinTE was not properly registered under Section 361. *See id.* ¶¶ 112, 115, 122, 129, 141, 146. Defendants argue that all the statements were either (1) statements of opinion that were not materially false or misleading because Defendants actually and reasonably held the opinion, or (2) statements of fact that were true when made. Defendants have the better of the argument.

1. Opinion Statements

All but one of the Section 361 statements challenged by Plaintiffs are statements of Defendants' belief regarding the propriety of Section 361 registration. *See* Dkt. 77 ¶¶ 111, 121, 128, 140, 145. Prior to PolarityTE's announcement that it would seek Section 351 registration, the company told investors in its SEC filings, "We believe our FDA-registered SkinTE and OsteoTE products satisfy the applicable criteria for regulation as a 361 HCT/P and are therefore exempt from FDA requirements for premarket approval or clinical studies." Dkt. 54-5 at 34, Dkt. 77 ¶ 121.[2] And after announcing its change in regulatory strategy, the company stood by its opinion: "We still believe

[2] Similar statements are quoted in paragraphs 111 and 128 of the Second Amended Complaint.

that SkinTE is appropriately regulated as a 361 HCT/P. However . . . we believe that the FDA may disagree with our interpretation if we sought a formal designation of SkinTE's regulatory classification, and that it therefore is prudent to pursue a strategy to file an investigational new drug application ('IND') and thereafter a biologics license application ('BLA') for SkinTE." Dkt. 54-9 at 33; Dkt. 77 at 140.[3]

These are statements of Defendants' beliefs, and therefore their falsity allegations must clear the "higher pleading standard" for opinion statements. *Hampton v. root9B Techs, Inc.*, 897 F.3d 1291, 1299 (10th Cir. 2018). Plaintiffs cannot satisfy their burden by alleging "only that an opinion was wrong." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S.Ct. 1318, 1332 (2015). Plaintiffs must allege particular facts showing that the speaker did not actually or reasonably hold the stated belief. *See Nakkhumpun v. Taylor*, 782 F.3d 1142, 1159 (10th Cir. 2015) (citing *Omnicare*, 135 S. Ct. at 1326–27).

Plaintiffs' falsity allegations do not meet this standard. First, Plaintiffs have not alleged with particularity that Defendants did not actually believe that SkinTE qualified for registration under Section 361. Plaintiffs claim that "Lough, and therefore PolarityTE, did not actually beileve [sic] SkinTE was properly registered under Section 361." Dkt. 77 ¶ 123. Plaintiffs cite in support of this a statement by an anonymous former employee that Lough refused to discuss whether SkinTE was properly registered, and that if anyone disagreed with him, he would "chop their head off." Dkt. 77 ¶ 78. Plaintiffs ask the Court to infer from this that Lough suppressed debate because he knew that SkinTE was improperly registered. Defendants argue to the contrary that these same facts show that Lough adamantly believed Section 361 Registration was appropriate. The Court agrees with

[3] A similar statement is quoted in paragraph 145 of the Second Amended Complaint.

Defendants' interpretation, finding that the allegations in the Complaint do not properly allege that Lough did not believe that Section 361 Registration was appropriate.

Plaintiffs then present the allegations of another anonymous former employee who claims that once Dr. Lough left PolarityTE, there were discussions of whether to change SkinTE's registration. *Id.* ¶ 93. The mere fact that conversations about SkinTE's registration status occurred does not demonstrate that PolarityTE's opinion statements were not sincere. And the confidential witness does not claim that any of the individual Defendants were present at those meetings, let alone that PolarityTE executives were known to believe that Section 361 registration was not appropriate for SkinTE. Thus, the allegations do not support a finding that Defendants did not sincerely believe that SkinTE qualified for Section 361 registration.

Plaintiffs have also failed to allege with particularity that Defendants' opinion about SkinTE's registration was not reasonably held. To plead falsity under this theory, Plaintiffs must "identify particular (and material) facts going to the basis" of PolarityTE's opinion regarding Section 361 registration for SkinTE and show that omission of those facts made the "statement at issue misleading to a reasonable person reading the statement fairly and in context." *Omnicare*, 135 S. Ct. at 1332. The complaint does not meet this burden.

Plaintiffs argue that PolarityTE's representations about its belief that Section 361 applied to SkinTE registration were misleading because the company "knew" that SkinTE was not minimally manipulated and omitted this fact from its statements. *See* Dkt. 77 ¶¶ 112, 122, 129, 141 146. But Plaintiffs have the burden to allege with particularity that "the real facts" about SkinTE "were not provided" to investors. *Omnicare,* 135 S. Ct. at 1328. In other words, Plaintiffs need to plausibly allege that SkinTE is more than minimally manipulated, and that this fact was not disclosed to investors. Plaintiffs have not met this burden because they have presented only speculation about how SkinTE

is made to show that the product is more than minimally manipulated, and that speculation is based on publicly available sources of information that investors were free to review.

Plaintiffs' claim that SkinTE is more than minimally manipulated is based on an example from an FDA guidance document, a picture from PolarityTE's 10-K, and a 2018 article by a stock analyst. *See* Dkt. 77 ¶¶ 74-76. Plaintiffs try to argue that these materials prove that SkinTE is not minimally manipulated because they show that PolarityTE turns "solid skin" into a "paste" and allegedly combines skin with "a number of additives, including growth factors." *See* Dkt. 77 ¶¶ 75, 122. Plaintiffs further claim that PolarityTE "grinds" a patient's skin sample to convert it into paste, and then cite FDA guidance published in November 2017 stating that a grinding process would "generally" qualify as more than minimal manipulation. *Id.* ¶ 74.

These allegations are speculative and do not state a claim for securities fraud. First, Plaintiffs identify no particular facts to show that PolarityTE "grinds" a patient's skin sample or applies growth factors to create SkinTE, and instead offer only their interpretation of publicly available sources of information. Significantly, these sources are the same sources rejected by the *PolarityTE I* court. *See PolarityTE I*, 2020 WL 6873798, at *8 ("Given that neither Plaintiffs nor the articles they rely on can identify the processes used to create SkinTE . . . it is difficult to conclude that Plaintiffs have plausibly alleged that PolarityTE lacked any factual basis for its opinion statements.").

Second, the sources which Plaintiffs rely on—FDA guidance, PolarityTE's SEC filings, and news reports—were all available to investors and provided context for PolarityTE's opinion statements. Plaintiffs have thus failed to plausibly allege that PolarityTE omitted particular and material facts about SkinTE from its opinion statements and thereby rendered the statements misleading to a reasonable person reading them fairly and in context.

Plaintiffs also argue in their opposition brief that Defendants' opinion statements were false and misleading because they were not based on a meaningful internal inquiry and were contradicted

by the company's decision to change its registration strategy. Plaintiffs have the burden to show that PolarityTE's "legal opinions" were not supported by "some meaningful legal inquiry." *Omnicare* at 1328. Nowhere in the complaint do Plaintiffs allege that PolarityTE failed to conduct a legal review of whether Section 361 registration was appropriate prior to registering SkinTE under that pathway. And while Plaintiffs allege that Dr. Lough was insistent that Section 361 applied, Plaintiffs do not allege that PolarityTE's attorneys or any other experts on FDA regulations advised Dr. Lough or the company that Section 361 registration was inappropriate. *See Omnicare*, 135 S.Ct. at 1329 (explaining that one way to plead falsity of a statement of legal compliance is to allege that a company made the statement "in the face of its lawyers' contrary advice").

Instead, Plaintiffs allege that unnamed employees may have believed that SkinTE was registered under the "wrong" section, but this is not sufficient to plead falsity of the Section 361 opinion statements. Reasonable investors do not "expect that every fact known to an issuer supports its opinion statement." *Omnicare*, 135 S. Ct. at 1329. "Every business will have employees that disagree on the correct strategy," especially "in businesses involved in emerging technologies." *Exkae Ltd. v. Domo, Inc.*, No. 2:19-CV-781-DAK-DAO, 2020 WL 7352735, at *6 (D. Utah Dec. 15, 2020). The federal securities laws do not require companies to detail "every concern that every employee has." *Id.*

Just as debate among employees regarding SkinTE's registration status does not show that PolarityTE lacked a reasonable factual or legal basis for its registration opinion, neither does the subsequent expression of disagreement from the FDA during informal discussions about SkinTE's registration status. Plaintiffs "cannot state a claim by alleging only that an opinion was wrong" in the eyes of a regulator, their complaint must allege facts that "call into question the issuer's basis for offering the opinion." *Omnicare,* 135 S.Ct. at 1332. Plaintiffs have not alleged the particular reasons for the FDA's disagreement or any other specific facts that would undermine the basis for

PolarityTE's registration opinion. The FDA's subsequent disagreement with Defendants' interpretation of the registration regulations does not mean that Defendants lacked any factual basis for their opinion at the time of the statements. *See PolarityTE I*, 2020 WL 6873798, at *9 (holding that the plaintiffs' allegations regarding the FDA's preliminary assessment did not support a finding that PolarityTE lacked any factual basis for its registration opinion). Neither does the company's change in business strategy to pursue Section 351 registration. *See In re Diebold Nixdorf, Inc. Sec. Litig.*, No. 19-CV-6180 (LAP), 2021 U.S. Dist. LEXIS 62449, at *31 (S.D.N.Y. Mar. 30, 2021) (holding that a company's "change in business strategy" does not render its "past disclosures" regarding its registration opinion misleading).

For these reasons, the Court holds that Plaintiffs have failed to adequately plead falsity for the opinion statements cited in paragraphs 111, 121, 128, 140 and 145 of the complaint.

2. Statement of Fact

In addition to the statements phrased as opinions, Plaintiffs also challenge the following statement of fact from PolarityTE's 10-K filed with the SEC on January 30, 2018:

> Unlike products regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") and/or the Public Health Service Act as drugs, devices, or biologics, which require multi-phase clinical trials and premarket approvals, our SkinTE product is regulated by the FDA as human cells or tissues intended for implantation.

Dkt. 77 ¶ 114.

Plaintiffs allege that the statement was false because "SkinTE was regulated by FDA [under Section 351]" at the time of the 10-K filing. Dkt. 77 ¶ 115. Defendants argue that Plaintiffs have not sufficiently alleged falsity because the statement was literally true when made—on the date that PolarityTE filed the 10-K, SkinTE was self-registered with the FDA under Section 361 and was not subject to FDA regulations requiring multi-phase clinical trials and premarket approval as a result.

The Court agrees with Defendants. It is undisputed that the HCT/P scheme is one of self-registration. A company can choose which regulatory pathway to pursue, and a product is registered—and therefore regulated—under that section until the company or the FDA decide otherwise. It was therefore not false or misleading for PolarityTE to tell investors in January 2018 that SkinTE was not regulated as a drug, device, or biologic before the company chose to pursue Section 351 registration. *See PolarityTE I*, 2020 WL 6873798 at *8 ("The statements that SkinTE was registered under Section 361, all of which were published before . . . SkinTE's deregistration, were true. SkinTE was registered under Section 361 during the time when all these statements were made.").

B. Statements Regarding PolarityTE's Manufacturing Processes and SkinTE Dosing

The second category of challenged statements concern PolarityTE's manufacturing processes and quality systems.[4] Four of the statements come from PolarityTE's 10-K filings and represent to investors that PolarityTE has "manufacturing processes and quality systems" that allow the company to "receive a specimen, qualify the incoming tissue, process and manufacture the cell/tissue product, and perform ongoing quality control and assurance work prior to shipping." Dkt. 77 ¶¶ 116, 119, 125, 147.

Two of the statements describe the dosing of SkinTE. In PolarityTE's 2019 10-K, the company told investors that in "the application of SkinTE to date we have been able, when applicable to a particular case, to collect from a patient a skin tissue sample 5 cm^2 in size or less and produce enough SkinTE to treat a wound 30x greater in size than the skin collected." Dkt. 77 ¶ 131. In an investor call on November 9, 2020, Defendant Hague made the following statement:

> On the dosing side, the beauty of SkinTE has always been that we could take a relatively small harvest and treat significant open wound. We've proven that both in our real-world experience and pre-clinically, but we need to put just a little bit more

[4] Plaintiffs refer to these statements as the "Potency Assay Statements." Defendants call them the "Form 483 Statements."

> work into categorizing that and validating that more specifically. So that ultimately, we can come to FDA and say that going forward, a harvest size of 'x' equates to a certain yield or dosage of product, which can then treat a certain wound size range of 'x' to 'y'. We need to do that a little bit more formally, as I've said, and to validate the work that we've done previously.

Dkt. 54-30 at 11, Dkt. 77 ¶ 142.

Plaintiffs allege that these statements were materially false and misleading because the Company failed to correct the issues identified by the FDA on Form 483 following its inspection of the Company's manufacturing facility in July 2018. Dkt. 77 ¶¶ 116, 119, 125, 131, 142, 147. According to Plaintiffs, one of the Form 483 observations was that PolarityTE did not have a "potency assay,"[5] and that statements by the Company were materially false and misleading by omission of the same. Defendants argue that Plaintiffs have not sufficiently alleged that statements made after July 2018 were materially misleading by omission. The Court agrees with Defendants.

Defendants argue that Plaintiffs have not sufficiently alleged that statements made in 2020 and 2021 about PolarityTE's manufacturing processes and the dosing for SkinTE were materially misleading by omission. *See* Dkt. 77 ¶¶ 131, 142, 147. Plaintiffs allege that the statements were misleading by omission because the Form 483 and the clinical hold letter issued by the FDA show that PolarityTE did not have a potency assay for SkinTE. *See id.* ¶¶ 132, 143, 148. The Court concludes that Plaintiffs have not met their burden to allege that the challenged statements were materially misleading for two reasons.

First, even if the Court assumes that one of the Form 483 observations shows that PolarityTE did not have a potency assay in July 2018, Plaintiffs have not met their burden to plead specific facts that show PolarityTE lacked a potency assay at the time the challenged statements were made in 2020

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[5] A potency assay measures the biological activity of a product, meaning its ability to produce a specific result. Dkt. 77 ¶ 84.

and 2021. The only allegation Plaintiffs offer in this respect is a citation to the clinical hold letter received by PolarityTE in September 2021. *See* Dkt. 54-26. Plaintiffs cite to the following excerpt from the letter: "As we mention in our Pre-IND correspondence (sent Feb 4, 2021) and IR comment (sent August 5, 2021), a potency assay should assess the biological function that is relevant to the mechanism of action (MOA) of your product." Dkt. 77 ¶ 98. This is not a particular fact showing that PolarityTE did not have a potency assay in February 2021 or August 2021. The language quoted by Plaintiffs is a reference to the FDA's definition of a potency assay provided in prior correspondence.

Other portions of the clinical hold letter further contradict Plaintiffs' assertion that PolarityTE did not have a potency assay in 2020 or 2021. The letter suggests that the company had proposed a potency assay to FDA: "Please provide potency assay information . . . to show that your proposed potency assays will consistently reflect your product's relevant biological properties." Dkt. 54-26 at 2. The issue was not a lack of a potency assay, but whether the FDA agreed that "the proposed potency assay matrix" was appropriate. *Id.* at 1. Given the inconsistencies between the clinical hold letter and Plaintiffs' allegations, and considering that Plaintiffs have not offered any other specific facts to show that PolarityTE did not have a potency assay for SkinTE in 2020 or 2021, the Court concludes that Plaintiffs have failed to meet their burden to show that the statements in paragraphs 131, 142 and 147 were false or misleading when made.

Second, one of the challenged statements appears to disclose to investors the very information about SkinTE's potency assay that Plaintiffs claim was omitted. Plaintiffs cite the following statement from a November 9, 2020 investor call:

> On the dosing side, the beauty of SkinTE has always been that we could take a relatively small harvest and treat significant open wound. We've proven that both in our real-world experience and pre-clinically, but we need to put just a little bit more work into categorizing that and validating that more specifically. So that ultimately, we can come to FDA and say that going forward, a harvest size of 'x' equates to a certain yield or dosage of product, which can then treat a certain wound size range of 'x' to

> 'y'. We need to do that a little bit more formally, as I've said, and to validate the work that we've done previously.

Dkt. 77 ¶ 142. Plaintiffs also claim that this statement was false and misleading "because PolarityTE lacked any adequate potency assay and therefore could not prove the appropriate dosage of SkinTE for a wound of a specific size." *Id.* ¶ 143. Plaintiffs' allegation is contradicted by the text of the statement, which tells investors that PolarityTE's needed to put "a little bit more work into categorizing" and "validating" the dosing for SkinTE. For this reason, the Court is not convinced that Plaintiffs have met their burden to allege with particularity that the statements in paragraphs 142 and 147 of the complaint were materially misleading by omission.

C. FDA Enforcement Discretion Statement

The last category of challenged statements relates to the FDA's enforcement discretion policy for HCT/P. In an April 30, 2020 press release, PolarityTE announced that it planned to pursue an IND application for SkinTE based on "preliminary views expressed by FDA." Dkt. 77 ¶ 135. The Company explained that the FDA "ha[d] not asked the Company to stop marketing SkinTE as a [HCT/P]" and that the product would "remain available under a limited sales and marketing program, subject to the Company's future discussions with FDA." *Id.* ¶ 137.

Plaintiffs allege that the press release was false or misleading because it did not disclose (a) the substance of the FDA's preliminary views on SkinTE's registration or (b) that PolarityTE could only sell SkinTE until the end of FDA enforcement discretion. The Court concludes that the statement was not materially misleading by omission on this basis.

First, Plaintiffs have not alleged a duty to disclose the FDA's "preliminary views." The FDA never made an official determination regarding SkinTE's registration status, and PolarityTE was not required to disclose the details of the FDA's "interim feedback." *See In re EDAP TMS S.A. Sec. Litig.*, 2015 WL 5326166, at *12 (S.D.N.Y. Sept. 14, 2015) (collecting cases for the proposition that there is no duty to disclose interim FDA feedback).

Second, a reasonable investor would not be misled by PolarityTE's statement that SkinTE would remain available "subject to the Company's future discussions with FDA" because the Company warned investors, "It is not customary for the FDA to allow wide-spread commercial sales of a product subject to the BLA." Dkt. 54-9 at 22. PolarityTE also advised, "We do not know, and cannot predict, whether FDA will allow us to continue selling SkinTE while our BLA is pending." Dkt. 54-10 at 23, Dkt. 54-19 at 25. Plaintiffs argue that the risk disclosures are not effective because company knew that FDA enforcement discretion would end in May 2021 and had already decided to seek Section 351 registration for SkinTE, but Plaintiffs do not cite any particular facts to show that Defendants knew the FDA would not allow PolarityTE to continue to sell SkinTE while its BLA was in progress. Without such facts, Plaintiffs have not met their burden to show that PolarityTE omitted information from its press release that was necessary to make the statement not misleading.

D. PolarityTE's Risk Disclosures

The Court is also persuaded by Defendants' argument that the statements challenged by Plaintiffs are not false or misleading because PolarityTE disclosed all the information that Plaintiffs allege was material and concealed from the market. To prevail an on omissions theory of falsity, Plaintiffs must plead facts showing that Defendants failed to state a fact necessary to make a statement not materially misleading. *See* 15 U.S.C. § 78u–4(b)(1). The converse of this rule is that there can be no fraud claim where Defendants disclosed all material facts to investors.

With respect to SkinTE's registration status, PolarityTE warned that HCT/Ps were subject to an evolving regulatory regime and that the FDA or others may disagree with its registration opinion. Dkt. 54-2 at 36; Dkt. 54-8 at PDF p. 18; Dkt 54-9 at 34, Dkt. 54-12 at 13. When discussing the IND application for SkinTE, the company cautioned investors that chemistry, manufacturing, and control issues may arise and lead to a clinical hold. Dkt 54-1 at 18, 23; Dkt 54-9 at 34–35;Dkt. 54-20 at 3, 9, 13. PolarityTE also disclosed the Form 483 to investors and informed them that the company needed

to perform additional work on its potency assay. Dkt. 54-1 at 22–23; SAC ¶ 142. And, as discussed above, PolarityTE told investors that SkinTE sales would have to end in May 2021 in the absence of continued enforcement discretion. Dkt. 54-1 at 1, 8, 24, 28, 39; Dkt. 54-10 at 23–24, Dkt. 54-19 at 25.

These disclosures are "fatal to plaintiffs' allegations that defendants deliberately withheld material information from investors." *In re Curaleaf Holdings, Inc. Sec. Litig.*, 519 F.Supp.3d 99, 107 (E.D.N.Y. 2021). PolarityTE "publicly and repeatedly acknowledged the very information that plaintiffs contend it concealed" regarding SkinTE. *Id.* The Court concludes that PolarityTE's extensive disclosures are an independent reason to dismiss all the statements challenged in the complaint. *See In re Progress Energy, Inc. Sec. Litig.*, 371 F.Supp.2d 548, 552 (S.D.N.Y. 2005) ("[T]here can be no omission where the allegedly omitted facts are disclosed.").

II. Control Person Claims

In addition to their Section 10(b) claim, Plaintiffs allege a violation of Section 20(a) of the Exchange Act against the individual Defendants. A prama facie case of control person liability requires Plaintiffs to demonstrate "(1) a primary violation of the securities laws and (2) 'control' over the primary violator by the alleged controlling person." *Maher v. Durango Metals, Inc.*, 144 F.3d 1302, 1305 (10th Cir. 1998). As Plaintiffs fail to establish a primary violation of the securities laws for the reasons set forth above, the Court dismisses the control person claims against the individual Defendants.

CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendants' motion and hereby **ORDERS** this matter dismissed, with prejudice.

* * *

Dated 4/19, 2023.

BY THE COURT:

BRUCE S. JENKINS
United States District Judge

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